

**Exhibit E 510(k) SUMMARY - Misonix SonicOne Ultrasonic Wound Care System and Accessories**

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92.

**1. Submitter's Identification**

Submitter's Name: MISONIX INCORPORATED  
Address: 1938 New Highway, Farmingdale, NY 11735  
Telephone Number: 516-694-9555  
Contact Person: Ronald R. Manna  
Date Prepared: August 9, 2010

**2. Name of Device**

Proprietary Name: Misonix SonicOne Ultrasonic Wound Care System and Accessories  
Common/Usual Name: Ultrasonic Surgical System  
Ultrasonic Surgical Aspirator  
Classification Name: Instrument, Ultrasonic Surgical

**3. Predicate Device Information**

Predicate Devices Arobella Medical LLC AR 1000 Ultrasonic Wound Therapy System K062544  
Misonix Inc. Alliger Ultrasonic Surgical System AUSS-6 K050776  
Microtek Medical Inc. Equipment Drapes K050322

**4. Device Description**

The SonicOne Ultrasonic Wound Care System is comprised of a generator, which feeds a 22.5 kHz electrical signal to a piezoelectric crystals mounted in a hand-held handpiece; the crystals then vibrate at the same frequency. The titanium tip attached to the handpiece amplifies the vibration. An irrigation unit is provided to introduce irrigation solution to the operative site. Accessories include probe tips, wrenches, sterile and non sterile tube sets and sterile Surgical Procedure bags and handpiece sheaths.

5. **Intended Use:** The Misonix SonicOne Ultrasonic Wound Care System and Accessories are indicated for use in the debridement of wounds, such as, but not limited to, burn wounds, diabetic ulcers, bedsores and vaginal ulcers, soft tissue debridement and cleansing of the surgical site in applications in which, in the physician's judgement would require the use of an ultrasonic aspirator with sharp debridement.
6. **Comparison to Predicate Device** SonicOne Ultrasonic Wound Care System and Accessories are similar in design, material and operating parameters to the Misonix Inc. AUSS-6 Ultrasonic Surgical Aspirator and the Arobella Medical LLC AR 1000 Ultrasonic Wound Therapy System.

7. **Safety and Performance Data**

The Misonix SonicOne Ultrasonic Wound Care System and Accessories have been designed and tested to pass the following Voluntary Standards:

IEC 60601-1*	Medical Electrical Equipment, Part 1: General Requirements for Safety
IEC 60601-1-2:2001	Medical Electrical Equipment General Requirements for EMC
FCC Part 18	EMC Requirements
ISO 10993-1:2009	Biological evaluation of medical devices —Part 1: Evaluation and testing
ISO 10993-7:2008	Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals
ISO 15223-1:2007/A1:2008	Medical devices —Symbols to be used with medical device labels, labeling, and information to be supplied —Part 1: General requirements

7. **Software Validation** This device does not contain software.
8. **Sterilization Validations** Validation statements are contained in Exhibit J.
9. **Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The SonicOne is identical to the AUSS-6 Ultrasonic Surgical Aspirator cleared under 510K #K050776. Therefore, no new Non-Clinical Tests have been performed in anticipation of this submission.

10. **Discussions of Clinical Tests Performed**

The FDA has cleared all indications for use in the predicates. As such, no additional clinic data was obtained in anticipation of this submission.

11. **Conclusions**

Misonix Inc. can state that the SonicOne is substantially equivalent in Mode of Operation, Hardware Design and Output Parameters to the Arobella Medical AR 1000 and the Misonix Inc. AUSS-6. Based upon the system and hardware validations described herein, the Misonix Inc. believes the SonicOne Ultrasonic Wound Care System and Accessories pose no new issues of safety or efficacy when used for soft and hard tissue ablation during wound treatment.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

DEC - 1 2011

Misonix Inc.  
% Mr. Ronald R. Manna  
1938 New Highway  
Farmingdale, New York 11735

Re: K112782

Trade/Device Name: Misonix SonicOne® Ultrasonic Wound Care System and Accessories  
Regulation Number: 21 CFR 878.4410  
Regulation Name: Low energy ultrasound wound cleaner  
Regulatory Class: Class II  
Product Code: NRB, FQH  
Dated: November 02, 2011  
Received: November 03, 2011

Dear Mr. Manna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Mark N. Melkerson

Director

Division of Surgical, Orthopedic  
and Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Exhibit C      Indications for Use Statement

K112782

Device Name: Misonix SonicOne<sup>®</sup> Ultrasonic Wound Care System and Accessories

The Misonix SonicOne Ultrasonic Wound Care System and Accessories are indicated for use in the debridement of wounds, such as, but not limited to, burn wounds, diabetic ulcers, bedsores and vaginal ulcers, soft tissue debridement and cleansing of the surgical site in applications in which, in the physician's judgment would require the use of an ultrasonic aspirator with sharp debridement.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE  
IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   X    
(Per 21 CFR 801.109)

or

Over-The-Counter Use \_\_\_\_\_

Neil R. Dyer for MAM  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K112782